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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2401-2450

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. DONALD KINGSLEY, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., November 29, 1948.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2401. Misbranding of various formula drugs and androgenic hormone. U. S. v. 9 Cartons, etc. (F. D. C. No. 20272. Sample Nos. 29661-H to 29665-H, incl.)

LIBEL FILED: June 20, 1946, Northern District of California; amended libel filed June 20, 1947.

ALLEGED SHIPMENT: The drugs were shipped by Basic Endocrines Sales Co., Inc., from Salt Lake City, Utah, on or about March 5 and 29 and April 10, 1946; and a number of booklets and pamphlets were shipped on or about April 18 and November 13, 1945, from Seattle, Wash., by the National Lithographing Co., at the order of Basic Endocrines Sales Co., Inc.

PRODUCT: 9 cartons, each containing 3 packages, of No. 3 Formula GE-2, 19 cartons, each containing 3 packages, of No. 6 Formula GE-5, 9 cartons, each containing 3 packages, of No. 14 Formula GH-3F, 34 cartons, each containing 3 packages, of No. 23 Formula GH-11, and 88 cartons of androgenic hormone at San Francisco, Calif., together with 106 booklets entitled "Basic Endocrines" and 300 pamphlets entitled "Androgenic Substance in Corn Oil."

LABEL, IN PART: "No. 3 Formula GE-2 30 Capsules Each Capsule contains: (Apoth) Thyroid (U. S. P.) $\frac{1}{10}$ gr., Anterior Pituitary (N. F.) $\frac{1}{2}$ gr., Ovarian Residue (N. F.) 3 grs., and Vegetable base q. s."; "No. 6 Formula GE-5 30 Capsules Each Capsule contains: (Apoth) Cardiac Substance 5 grs., and Vegetable base q. s."; "No. 14 Formula GH-3F 30 Capsules Each Capsule

*For sale under name of another drug, see No. 2403; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2403, 2416.

contains: (Apoth) Thyroid (U. S. P.) $\frac{1}{2}$ gr., Whole Pituitary (N. F.) $\frac{1}{4}$ gr., Suprarenal Substance (N. F.) $\frac{2}{3}$ gr., Ovarian Residue (N. F.) $1\frac{1}{2}$ grs., Placental Substance $\frac{1}{2}$ gr., and Vegetable base q. s."; "No. 23 Formula GH-11 30 Capsules Each Capsule contains: (Apoth) Gastric Mucin 6 grs., Okra $1\frac{1}{2}$ grs."; and "30 Perles No. 105 Androgenic Hormone $\frac{1}{2}$ Capon Unit Per Perle Androgenic Substance derived from testicular tissue dissolved in corn oil."

NATURE OF CHARGE: *No. 3 Formula GE-2.* Misbranding, Section 502 (a), the label statement "Each Capsule contains: (Apoth) Thyroid (U. S. P.) $\frac{1}{10}$ gr., Anterior Pituitary (N. F.) $\frac{1}{3}$ gr., Ovarian Residue (N. F.) 3 grs. * * * No claim for estrogenic or Progestational activity. Contains no known therapeutically or physiologically active constituent derived from Anterior Pituitary or Ovarian Residue principles, for which recognized methods of assay exist" was misleading since it failed to reveal the material fact that the anterior pituitary and ovarian residue in the article contributed nothing to its therapeutic effects. Further misbranding, Section 502 (a), the statement in the booklet as to the article, "Indications: A rational organotherapy as an auxiliary support in symptoms of hypoovarian, amenorrhea, dysmenorrhea, painful breasts and hot flushes of the menopause," was false and misleading since the article was not effective to fulfill the promises of benefit stated and implied; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

No. 6 Formula GE-5. Misbranding, Section 502 (a), the label statement "Each Capsule contains: (Apoth) Cardiac Substance 5 Grs. * * * Contains no known therapeutically or physiologically active constituent derived from cardiac principles for which recognized methods of assay exist" was misleading since it failed to reveal the material fact that the cardiac substance in the article possessed no medicinally useful properties. Further misbranding, Section 502 (a), the statement in the booklet as to the article, "Indications: A rational organotherapy as an auxiliary support in symptoms of muscular weakness of the heart and in some cardiac conditions," was false and misleading since the article was not effective to fulfill the promises of benefit stated and implied; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

No. 14 Formula GH-3F. Misbranding, Section 502 (j), the article, by reason of its thyroid content, was dangerous to health when used in the dosage and with the frequency prescribed and recommended in its labeling, i. e., "1 to 3 daily."

No. 23 Formula GH-11. Misbranding, Section 502 (a), the statement "Indications: A rational organotherapy as an auxiliary support in gastro-duodenal ulcerations, inflammations," which statement related to the article and appeared in the booklet, was false and misleading since the article was not effective to fulfill the promises of benefit stated and implied; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

Androgenic hormone. Misbranding, Section 502 (a), the label statement " $\frac{1}{2}$ Capon Unit Per Perle * * * Androgenic Substance derived from testicular tissue * * * Directions: One to six perles or as indicated" was misleading since it failed to reveal the material facts that $\frac{1}{2}$ capon unit androgenic substance per perle administered in doses of one to six perles is essentially inert; and the following statements relating to the article and appearing in the booklet and pamphlets were false and misleading since the article was not effective to fulfill the promises of benefit stated and implied: (Booklet) "Rationale: Some clinicians have found male sex hormones of value as a replacement therapy in conditions associated with certain types of sexual deficiencies, such as hypogonadism, impotence, under developed genitalia, premature senility, benign prostatic hypertrophy, male climacteric and functional insufficiency" and (pamphlet) "1. Development and maintenance of the prostate, seminal vesicles, spermatogenic elements, the accessory sexual apparatus, including control over the energy with which spermatozoa pass through the various tubes. 2. Secondary male characteristics such as growth and distribution of hair on the head and body. 3. Nervous system. Increases resistance of the central system to fatigue. 4. Stimulation of libido and potency. 5. Control over fat distribution of certain types. 6. Synergism with the female hormone. Indications and Uses. Some clinicians have found male sex hormones of value as a replacement therapy in conditions associated with certain types of sexual deficiencies, such as hypogonadism, impotence, under developed genitalia, premature senility, benign prostatic hypertrophy, male

climacteric and functional insufficiency." Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: June 8, 1948. The Basic Endocrines Sales Co., Inc., having been permitted to withdraw its claim in the matter, judgment of condemnation was entered and the products were ordered destroyed.

2402. Misbranding of Electronic Device. U. S. v. 5 * * *. (F. D. C. No. 24176. Sample No. 6216-K.)

LIBEL FILED: January 14, 1948, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 13, 1947, by Saul Brothers, Inc., from Bronx, N. Y.

PRODUCT: 5 Electronic Devices at Pittsburgh, Pa.

LABEL, IN PART: "United Diathermy, Inc., Electronic Device Deluxe Model Serial No. 8408" [or other number] Short Wave Electrodes 27300 KC 115V."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of bursitis, arthritis, neuritis, neuralgia, sciatica, common forms of colds, lumbago, and chronic sinus conditions, which were the conditions for which the device was prescribed, recommended, and suggested in its advertising distributed with each device, i. e., a booklet entitled "Good Health brings Long Life and Happiness" disseminated and sponsored by and on behalf of the manufacturer and distributor of the device.

Further misbranding, Section 502 (j), the device was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling, i. e., a leaflet entitled "Instruction Sheet" which was shipped with each device and which contained the following statements: "180 Watt Output 60 Cycle 115 V. A. C. Instruction Sheet Important Read The Following Instructions Carefully Before Using This Apparatus: 1. Place connecting plug into wall socket. 2. Wires of electrode pads to be inserted in Outlets marked 'Electrodes'. 3. Before starting, make certain that: a. Time switch is in zero position; 4. Place electrode pads to the area to be treated, do not cross electrode pad wires. Proper spacing is essential. For example—Place a folded turkish towel between each electrode and the body. 5. Turn time switch to the right to the desired number of minutes. This time switch automatically starts the Short Wave, as you will note by the pilot light in the center of the panel. 6. Turn heat control to the right or to the left until lowest point of meter. Then turn to the right until desired amount of heat is obtained. If too hot turn back to left until you get a comfortable heat. 7. Heat should be comfortably warm—never hot. You will find it far more beneficial to take a longer and milder treatment, than a short treatment that is uncomfortably hot. An uncomfortably hot treatment is wrong and may result in a serious burn. 8. Any metal, in the path of the Short Wave should be avoided. Bed should be non-metallic. If made of metal, cover them up with a heavy mattress. 9. Caution: Unless otherwise instructed by a physician, do not use for: Menstruation or pregnancy Gastric Ulcers Malignant Tumor Acute inflammatory Condition. 10. If any further information is desired, please telephone or write this office."

DISPOSITION: One device was seized, and on February 25, 1948, a default decree of condemnation was entered and the device was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2403. Misbranding of estrogenic substances. U. S. v. International Hormones, Inc. Plea of guilty. Fine, \$500. (F. D. C. No. 20203. Sample Nos. 30083-H, 30084-H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against International Hormones, Inc., Brooklyn, N. Y.

ALLEGED SHIPMENT: On or about May 5 and August 24, 1945, from the State of New York into the State of California.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Estrogenic Substances in Sesame Oil Consisting of estrone, estradiol, estriol and other ketonic fractions derived from pregnant mares' urine" was false and

*See also Nos. 2401, 2402.